DEPARTMENT OF HEALTH & HUMAN SERVICES

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2002-DT-14

December 10, 2001

Mr. Cameron A. Mc Murry, President
Big Stone Bay Fishery, Inc.
10975 U.S. 23
Mackinaw City, MI 49701

Dear Mr. McMurry:

On August 16th & 17th, 2001 the Food and Drug Administration (FDA) conducted an inspection of your facility located at 10975 U.S. 23, Mackinaw City, MI. The inspection was conducted to determine compliance with the FDA's Seafood Hazard Analysis Critical Control Point (HACCP) Regulation (21 CFR 123) and the current Good Manufacturing Practice requirements for foods (GMP) (21 CFR 110).

During the inspection, the FDA investigators observed shortcomings in your system that are deviations from the principles of HACCP and the significant requirements of the program. The FDA investigators presented your firm with a form FDA-483 that provides the investigators' evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. In spite of some of the corrections you have made, we still find your firm is in violation of 21 CFR 123 and 110 causing your products to be deemed adulterated under the provisions of 21 U.S.C. 342(a)(4) because of the following:

1. You must fully document, in records, all corrective actions taken, in order to comply with 21 CFR 123.7(d). However, you did not document that a corrective action was taken when you deviated from your critical limit of a minimum cook temperature of [redacted] minutes for "hot smoked whitefish" (whole) at the smoking/cooking critical control point to control for pathogen survival.

2. You must implement the monitoring procedure of recording storage cooler temperatures [redacted] listed in your "Hot Smoked Fish" HACCP plan, in order to comply with 21 CFR 123.6(b). However, your firm failed to perform and document cooler temperatures at the beginning and end of each shift as outlined in

your "Hot Smoked Fish" HACCP plan on 6/8/01, 6/19/01, 7/7/01, 7/14/01, 7/16/01, 7/21/01, 7/30/01 and 8/5/01.

3. You must have a written HACCP plan to control any food hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for "Hot Smoked Fish Spread" and "Hot Smoked Fish Sausage" to control the food safety hazard of pathogen growth.

4. You must have sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11(c). However, your firm lacked sanitation monitoring records for "Smoked Whitefish" for 12 of 12 lots reviewed (lot numbers 6/7/01, 6/10/01, 6/22/01, 6/29/01, 6/26/01, 7/18/01, 7/10/01, 7/15/01, 7/19/01, 7/21/01, 7/30/01 & 8/14/01).

5. You must adequately monitor sanitation conditions and practices during processing, in order to comply with 21 CFR 123.11(b) & 21 CFR 110.37(a). However, your firm has not tested or evaluated the safety of the water used in processing "Hot Smoked Fish" since September 9th, 1998. Further, your firm did not monitor cleaning of all food-contact surfaces as frequently as necessary to protect against contamination of food as evidenced by our observations of a heavy oily residue and dark brown chunks of fish adhering to the smoking racks.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure or injunction.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Also, please include copies of any available documentation demonstrating that corrections have been made.

Your written reply should be directed to Mr. David M. Kaszubski, Director Compliance Branch, U.S. Food and Drug Administration, 1560 E. Jefferson, Detroit, MI 48207, telephone (313) 226-6260.

Sincerely,

Joann M. Givens
District Director
Detroit District